K090358

AUG 0 6 2009

ARCHITECT *i*Valproic Acid

510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Name:

Judi Wallach
Regulatory Affairs Specialist
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064

Device Name:

Reagents:

Classification Name: Valproic Acid test system
Trade Name: ARCHITECT *i*Valproic Acid Immunoassay
Common Name: Valproic Acid test
Governing Regulation: 862.3645
Device Classification: Class II
Classification Panel: Toxicology
Product Code: LEG

Calibrators:

Classification Name: Calibrator, drug specific
Trade Name: ARCHITECT *i*Valproic Acid Calibrators (A-F)
Common Name: Calibrator
Governing Regulation: 862.3200
Device Classification: Class II
Classification Panel: Toxicology
Product Code: DLJ

Legally marketed device to which equivalency is claimed:

AxSYM Valproic Acid (K941615)

Intended Use of Device:
The ARCHITECT *i*Valproic Acid assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of valproic acid, an anticonvulsant drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in monitoring levels of valproic acid to help ensure appropriate therapy.

Description of Device:
The ARCHITECT *i*Valproic Acid assay is a one-step *STAT* immunoassay for the quantitative measurement of valproic acid in human serum or plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex. Sample, anti-valproic acid coated paramagnetic microparticles, and valproic acid acridinium-labeled conjugate are combined to create a reaction mixture. The anti-valproic acid coated microparticles bind to valproic acid present in the sample and to the valproic acid acridinium-labeled conjugate. After washing, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). An indirect relationship exists between the amount of valproic acid in the sample and the RLUs detected by the ARCHITECT *i* System optics.

Comparison of Technological Characteristics:
The ARCHITECT *i*Valproic Acid assay utilizes Chemiluminescent Microparticle Immunoassay (CMIA) technology for the quantitative measurement of valproic acid, an anticonvulsant drug, in human serum and plasma. The AxSYM Valproic Acid assay utilizes Fluorescence Polarization Immunoassay (FPIA) technology for the quantitative measurement of valproic acid, an anticonvulsant drug, in serum or plasma.

Summary of Non-Clinical Performance:

The ARCHITECT *i*Valproic Acid assay is substantially equivalent to the AxSYM Valproic Acid assay in terms of precision, linearity, and interferences as demonstrated in non-clinical performance data in this 510(k) submission.

Summary of Clinical Performance:

The ARCHITECT *i*Valproic Acid assay demonstrated substantially equivalent performance to the AxSYM Valproic Acid assay with a correlation coefficient of 0.986.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Abbott Laboratories Inc.,
Diagnostic Division
c/o Ms. Judi Wallach
Senior Regulatory Affairs Specialist
100 Abbott Park Road, AP6C-2, Dept 049C
Abbott Park, IL 60064

AUG 0 6 2009

Re: k090358
Trade Name: Architect iValproic Acid Immunoassay and Architect iValproic Acid Calibrators (A-F)
Regulation Number: 21 CFR §862.3645
Regulation Name: Neuroleptic Drugs Radioreceptor Assay Test System
Regulatory Class: Class II
Product Codes: LEG, DLJ
Dated: June 24, 2009
Received: June 25, 2009

Dear Ms. Wallach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name: ARCHITECT *i*Valproic Acid

Indication for Use:

Reagents

The ARCHITECT *i*Valproic Acid assay is an *in vitro* chemiluminescent microparticle immunoassay (CMIA) for the quantitative measurement of valproic acid, an anticonvulsant drug, in human serum or plasma on the ARCHITECT *i* System with *STAT* protocol capability. The measurements obtained are used in monitoring levels of valproic acid to help ensure appropriate therapy.

Calibrators

The ARCHITECT *i*Valproic Acid Calibrators are for the calibration of the ARCHITECT *i* System with *STAT* protocol capability when used for the quantitative determination of valproic acid in human serum or plasma.

Prescription Use __X__ And/Or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k090358